

REMARKS/ARGUMENTS

In response to the Final Office Action of July 29, 2005, Applicants request re-examination and reconsideration of this application for patent pursuant to 35 U.S.C. 132.

Claim Status/Support for Amendments

Claims 1, 39, 40 and 44 have been amended. Claims 2-38 were cancelled in a previous response (filed on December 10, 2004). Claims 39-46 are withdrawn from consideration. It is understood that claims 39-46, drawn to the non-elected invention, will remain pending, albeit withdrawn from consideration on the merits at this time. If the examined claim of the Group I invention is deemed to be allowable, rejoinder of the remaining claims (39-46) in accordance with the decision in *In re Ochiai* is respectfully requested; since the remaining claims (39-46) are limited to the use of the biopolymer markers of claim 1 (the examined claim of the elected Group I invention).

Claim 1 is currently under examination. Claims 1 and 39-46 remain pending in the instant application.

No new matter has been added by the amendments to the claims made herein.

Claims 1, 39 and 44 were amended to recite the proper alternative expression and transition phrases to clearly indicate

the intended scope of the claims.

Claim 40 was amended to provide proper antecedent basis for the term "sample" as recited in parent claim 39.

Claims 39 and 44 were amended to delete the term "isolated".

Request for Rejoining of Claims

Considering that claims 39-46 are limited to the use of SEQ ID NO:1; SEQ ID NO:2 and SEQ ID NO:3 a search of these claims would encompass these specific sequences. The instant application is related in claim format to several other applications, both pending and issued, of which serial number 09/846,352 is exemplary. In an effort to maintain equivalent scope in all of these applications, Applicants respectfully request that the Examiner consider rejoining claims 39-46 in the instant application, which are currently drawn to non-elected Groups, with claim 1 of the elected Group under the decision in *In re Ochiai* (MPEP 2116.01), upon the Examiner's determination that claim 1 of the elected invention is allowable and in light of the overlapping search. If the biopolymer markers of SEQ ID NO:1; SEQ ID NO:2 and SEQ ID NO:3 are found to be novel, methods and kits limited to their use should also be found novel.

Interview with the Examiner

Applicants thank the Examiner for courtesies extended during her telephone interview with Applicants' representatives, Ferris Lander and Katharine Davis, on September 15, 2005.

The use of Markush language (alternative expression) and transitional phrases to delineate the scope of the claims was discussed. Both the Examiner and Applicants' representatives agreed that the amendments to the claims as presented herein are sufficient to overcome the rejection under 35 USC 112, second paragraph.

Rejection under 35 USC 112, second paragraph

Claim 1, as presented on May 9, 2005, stands rejected under 35 USC 112, second paragraph as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner asserts that claim 1 does not include a proper transition phrase "comprising" or "consisting of" in the claim. Accordingly, it is not clear as to what the sequence will encompass. The claim is in the proper Markush Format reciting selected from the group consisting of. However, while this language provides closed interpretation between SEQ ID NO:1; SEQ ID NO:2 and SEQ ID NO:3, it does not clearly identify Applicants' intended

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scope for SEQ ID NO:1; SEQ ID NO:2 and SEQ ID NO:3.

The "alternative expression" language of claim 1 has been amended herein, the Markush format has been replaced by "or" terminology (see MPEP 2173.05 (h) I, II). Claim 1 has also been amended to include the transition phrase "consisting of". The phrase "consisting of" is closed language and excludes any element, step or ingredient not specified in the claim (see MPEP 2111.03). Since claim 1 now recites an isolated biopolymer marker consisting of SEQ ID NO:1; consisting of SEQ ID NO:2 or consisting of SEQ ID NO:3, the scope is clearly delineated as limited to these specific peptides (SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3) as disclosed in the instant specification as originally filed at page 46, lines 8-18, thus excluding any additional amino acid residues or other elements.

Accordingly, Applicants have now clarified the metes and bounds of the claims and respectfully request that the above-rejection under 35 USC 112, second paragraph be withdrawn.

Rejections under 35 USC 101 and 35 USC 112, first paragraph

In the previous Office Action mailed on January 5, 2005, the Examiner rejected claim 1, as drawn to an isolated biopolymer marker consisting of SEQ ID NO:1, for failing to comply with the requirements of utility and enablement. In the Final Office Action

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mailed on July 29, 2005, the Examiner withdrew the rejections to claim 1, as drawn to SEQ ID NO:1, and applied the same rejections of claim 1 (under utility and enablement), as drawn to SEQ ID NO:3. The Examiner states at page 8 (with regard to utility) and page 13 (with regard to enablement) of the Final Office Action that applicant arguments against SEQ ID NO:1 are moot because sequences comprising SEQ ID NO:1 have been addressed under the art rejections herein. However, the amended claims currently include SEQ ID NO:3, which was free of the prior art. The Examiner asserts that the utility of the newly recited sequence (SEQ ID NO:3) is not provided in the disclosure.

At page 46, lines 8-18 of the instant specification as originally filed, the claimed SEQ ID NOS:1-3 are identified as fragments of the complement C3 precursor protein, i.e. SEQ ID NOS:1-3 are all part of the same protein. The Examiner applies US Patent 5,849,297 (Harrison et al.) as 102(b) art against claim 1 as drawn to SEQ ID NOS:1 and 2. US Patent 5,849,297 (Harrison et al.) discloses the entire protein sequence of human complement C3 (Figures 1A-B, SEQ ID NO:1 of Harrison et al.). The claimed peptides, SEQ ID NOS:1-3, are fragments of the entire protein sequence of human complement C3; see attached Figure 1B of Harrison et al., reference #1.

Applicants are confused as to why the Examiner indicates that

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the claimed SEQ ID NO:3 is free of the art when it is clearly disclosed in the same patent as the claimed SEQ ID NOS:1 and 2. Applicants are also further confused as to why the rejections of claim 1 under 35 USC 101 and 35 USC 112, first paragraph are still applicable against claim 1 as reading on SEQ ID NO:3 when these rejections are withdrawn as reading on SEQ ID NO:1.

In light of this confusion, Applicants respectfully submit the same response to the rejections (35 USC 101 and 35 USC 112, first paragraph) of claim 1 as reading on SEQ ID NO:3 as the response to the rejections of claim 1 as reading on SEQ ID NO:1.

Rejection under 35 USC 101

Claim 1, as presented on May 9, 2005, is rejected under 35 USC 101 because the claimed invention is allegedly not supported by either a specific, substantial, credible or asserted utility or a well-established utility.

Applicants respectfully disagree with the Examiner's assertion and draw her attention to pages 24-31 of the previous response filed on May 9, 2005.

Rejection under 35 USC 112, first paragraph

Claim 1, as presented on May 9, 2005, is rejected under 35 USC 112, first paragraph as allegedly failing to comply with the

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enablement requirement. The Examiner asserts that the claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains or with which it is most nearly connected, to make and/or use the invention. Furthermore, the Examiner asserts that since the claimed invention allegedly is not supported by a specific, substantial, credible or a well-established utility, one skilled in the art clearly would not know how to use the claimed invention.

Applicants respectfully disagree with the Examiner's assertion and draw her attention to pages 31-49 of the previous response filed on May 9, 2005.

Rejections under 35 USC 102

Claim 1, as presented on May 9, 2005, stands rejected under 35 USC 102 (b) as allegedly being anticipated by Harrison et al. (US Patent 5,849,297).

The Examiner states that Harrison et al. discloses sequences comprising or having SEQ ID NO:1 and SEQ ID NO:2. See GenCore protein search dated 8/5/04. Although the reference is silent with respect to sequences being biomarkers, this is deemed inherent to the biopolymer. In other words, the sequences set forth in the claim would inherently be markers. Applicants SEQ ID NO:1 and SEQ

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ID NO:2 are disclosed as sequence identification number 1 in the reference to Harrison. The Examiner alleges that therein the claimed sequence is taught.

The disclosure of Harrison et al. encompasses the entire amino acid sequence of the complement C3 protein. The claimed biopolymer markers SEQ ID NOS:1-3 are fragments of this entire amino acid sequence.

Claim 1, as instantly presented, recites specific markers (SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3). Furthermore, since "consisting of" is closed language and excludes any element, step or ingredient not specified in the claim (see MPEP 2111.03), the scope of the instant claim now encompasses only these three specific peptides (SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3) thus excluding the disclosure of Harrison et al. Nowhere does Harrison et al. specifically teach the claimed biopolymer marker sequences (SEQ ID NOS:1-3). Nor does Harrison et al. teach any peptide which is indicative of a link to Type II diabetes.

Accordingly, Applicants respectfully submit that the claim, as instantly presented, now distinguishes over the sequences taught by Harrison et al. and respectfully request that this rejection under 35 USC 102(b) be withdrawn.

Claim 1, as presented on May 9, 2005, stands rejected under 35 USC 102(a) as allegedly being anticipated by Harrison et al. (US Patent 6,221,657 B1).

The Examiner states that Harrison et al. discloses sequences comprising or having SEQ ID NO:1 and SEQ ID NO:2. See GenCore protein search dated 8/5/04. Although the reference is silent with respect to sequences being biomarkers, this is deemed inherent to the biopolymer. In other words, the sequences set forth in the claim would inherently be markers. Applicants SEQ ID NO:1 and SEQ ID NO:2 are disclosed as sequence identification number 1 in the reference to Harrison. The Examiner alleges that therein the claimed sequence is taught.

The disclosure of Harrison et al. encompasses the entire amino acid sequence of the complement C3 protein. The claimed biopolymer markers SEQ ID NOS:1-3 are fragments of this entire amino acid sequence.

Claim 1, as instantly presented, recites specific markers (SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3). Furthermore, since "consisting of" is closed language and excludes any element, step or ingredient not specified in the claim (see MPEP 2111.03), the scope of the instant claim now encompasses only these three specific peptides (SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3) thus excluding the disclosure of Harrison et al. No where does Harrison

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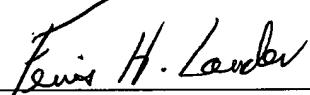
et al. specifically teach the claimed biopolymer marker sequences (SEQ ID NOS:1-3). Nor does Harrison et al. teach any peptide which is indicative of a link to Type II diabetes.

Accordingly, Applicants respectfully submit that the claim, as instantly presented, now distinguishes over the sequences taught by Harrison et al. and respectfully request that this rejection under 35 USC 102(a) be withdrawn.

CONCLUSION

In light of the foregoing remarks and amendments to the claims, it is respectfully submitted that the Examiner will now find the claims of the application allowable. Favorable reconsideration of the application is courteously requested.

Respectfully submitted,


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\Ns2\SERVER\CLIENT FILES\2100-2199\2132 -Syn-X\2132_000108 - Complement C3 Precursor
Biopolymer\Amendments\2132_108_AM2.wpd

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5,849,297

SEQ ID NO: 2

970 980 990 1000 1010 1020
 DIPPADLSQQ VPDTESETRI ~~LLOGTPVAQM~~ TEDAVDAERL KHLIVTPSGC GEQNMIGMTP

1030 1040 1050 1060 1070 1080
 TVIAVHYLDE TEQWEKFGLE KRQGALELIK KGYTQQLAFR QPSSAFAAFV KRAPSTWLTA

1090 1100 1110 1120 1130 1140
 YVVKVFSLAV NLIAIDSQVL CGAVKWLILE KQKPDGVFQE DAPVIHQEMI GGLRNNNEKD

1150 1160 1170 1180 1190 1200
 MALTAFVLIS LQEAKDICEE QVNSLPGSIT KAGDFLEAN Y MNLQR SYTVA IAGYALAO MG

1210 1220 1230 1240 1250 ^{SEQ ID NO: 3} 1260
 RLKGPLL NKF LTTAKDKNRW EDPGKQLYNV EATSYALLAL LQLKDEDEVP PVVRWLNEQR

1270 1280 1290 1300 1310 1320
 YYGGGGYGSTQ ATFMVFQALA QYQKDAPDHQ ELNLDVSQL PSRSSKITHR ~~IHWESASLLR~~ ^{SEQ ID NO: 1}
 of

1330 1340 1350 1360 1370 1380
 SEETKENEGF TVTAEGKGQG TLSVVTMYHA KAKDQLTCNK FDLKVTIKPA PETEKRPQDA ^{09/993,287}

1390 1400 1410 1420 1430 1440
 KNTMILEICT RYRGDQDATM SILDISM MTG FAPDTDDLKQ LANGVDRYIS KYELDKAFSD

1450 1460 1470 1480 1490 1500
 RNTLIIYLDK VSHSEDDCLA FKVHQYFNVE LIQPGAVK VY AYYNLEESCT RFYHPEKEDG

1510 1520 1530 1540 1550 1560
 KLNKLCRDEL CRCAEENCFI QKSDDKVTL ER LDKACEPG VDYVYKTRLV KVQLSND FDE

1570 1580 1590 1600 1610 1620
 YIMAIEQTIK SGSDEVQVGQ QRTFISPIKC REALKLEEKK HYLMWGLSSD FWGEKPNLSY

1630 1640 1650 1660
 IIGKDTWVEH WPEEDECQDE ENQKQCQDLG AFTESMVVF



FIG. 1B